

REMARKS/ARGUMENTS

The Final Office Action, mailed August 23, 2006, rejected claims 1-20. Applicants have amended Claims 4 and 17 back to the form as originally filed. Claims 1-20 remain pending in this application.

Claims 4 and 17 rejected under 35 U.S.C. §112, first paragraph

Claims 4 and 17 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner stated that he "could find no support in the specification for the limitation of "wherein the tube and inner core form a non-separable, solid stylet" [Office Action, paragraph 2]. Applicants believe that such support is found in the specification for such an embodiment. [See, Applicants' Specification, paragraph 52]. However, in response to this §112 rejection, Applicants have chosen, instead, to amend the claims 4 and 7 back to the form as originally filed. The original claims as filed are considered part of the original disclosure and hence this §112 rejection is removed.

Claims 1, 2, 5-11, 14, 17 and 18 rejected under 35 U.S.C. 102(b)

Claims 1, 2, 5-11, 14, 17 and 18 were rejected a second time under 35 U.S.C. 102(b) as being anticipated by Williams et al. (U.S. Pat. No. 6,214,016, hereinafter referred to as "Williams"). This rejection is respectfully traversed with a new argument.

Applicants' independent Claim 1 recites a stylet that has an "outer covering" and "an inner core" of different "elastic and buckling properties". Independent Claims 14 and 18 similarly refer to "an outer covering" and "an inner core material".

The Examiner has noted, that "Williams discloses a stylet (42 and 46), comprising an outer metallic covering (44 and col. 5, line 37), an inner core (46), and the outer and inner portions have different elastic and buckling properties (col. 5, line 37 and col. 6, line 8)." [Office Action, page 3, paragraph 4.] The outer tubular member 42, the inner tubular member 44, and the innermost member 46 (the stylet) are separate because they are "slidably movable within each other and are selectively positionable." [See, Williams, column 6, lines 60-63, and also Figure 6.]

This feature of "slidably movable" between all parts is a key feature of the Williams invention. As explained throughout Williams' specification, all of the elements must be movably slidable relative to each other (and therefore movably separate from each other) because Williams' device permits the stylet to curve or bend through tissue such as brain tissue. [See Williams, column 3, lines 1-19.] Indeed, in order to achieve the purpose of the design to provide curved entry into tissue, e.g., the brain, Williams's positioning device requires that all parts be movable with each other. "[T]he outer tubular member 42 has a greater rigidity than the inner tubular member 44, such that the outer tubular member 42 remains substantially linear when the inner tubular member 44 is positioned substantially within the outer tubular member. [Williams, column 4, lines 52-57.] In addition, "[w]hen exiting the outer tubular member, the inner tubular member elastically resumes its curvature and advances outwardly along a curved path into and through the organ." [Williams, column 3, lines 8-11]. The purpose

of each of the parts, stylet 46, inner tubular member 44, outer tubular member 42 is to permit the inner tubular member 44 to curve as it extends out from the more rigid outer tubular member 42. The innermost member or stylet 46 [Williams, column 6, line 7] simply extends further from the inner tubular member 44, and causes the catheter or lead 50 to curve and extend out. [See Williams, Figures 4, 5 and 6.] Importantly, all parts are slidably movable with respect to each other, as they must in order for the lead or catheter to take a curved path.

Applicants contend that Williams does not anticipate Applicants' independent Claims 1, 14 and 18 (and all dependent claims) because Applicants' specification describes a composite stylet that has an outer covering and inner core that are configured to be immovable with each other. Although Applicants' Claims 1, 14, 18 do not explicitly say that the outer covering and inner core are not movable with each other, the claims must be read in light of Applicants' specification and the purpose of the stylet as described in the specification. There is no discussion in Applicants' specification that the outer covering and inner core are movable with respect to each other during normal use as stylet and, as such, it would be strained reading to impart into Applicants' claims that the outer covering and inner core are movable with respect to each other.

Although Applicants' specification mentions [paragraphs 43 and 46] that a rod may be inserted into an outer covering, that does not mean, however, that the rod is movable with respect to the outer covering after the stylet is assembled or while the stylet is in use. There is no suggestion in Applicants' specification that the final assembled stylet has a movable inner core relative to the outer covering.

To the contrary, Applicants' stylet is intended to do the opposite -- the inner core is not movable with respect to outer covering while the stylet is in use. The specific purpose is to create a composite stylet having mechanical properties imparted by the outer covering and the inner core at the same time. [See Applicants' Specification, paragraphs 24, 29, 43 and 65 (second sentence).]

Applicants teach that the outer covering and inner core of the stylet are fixed relative to each other—not movable. The inner material may be a filling material [Applicants' Specification, paragraph 46]. Such a filling is likely to be stuck inside the outer covering and unlikely to be movable. That would certainly be the case should the filling hardened inside the outer covering. [Applicants' Specification, paragraph 47, last sentence]. More telling, however, is the specific detailed instruction in Applicants' Specification on how a core is placed inside a nitinol tube and the nitinol tube is drawn over the core by pulling through a die. The drawn assembly is heated to a temperature above 400 degrees C for several minutes to set the nitinol over a core. [Applicants' Specification, paragraph 52.] "To set" means to make the core immovable relative to the outer covering. Hence, there is no description or rationale in Applicants' description of a composite stylet to make the inner core movable relative to the outer covering because that is not a goal of Applicants' stylet.

Applicants' Claims 1, 14, and 18 would appear (without the benefit of reading the specification) to cover the device as described and shown in Williams. For Williams to anticipate the Claims 1, 14, and 18, these claims must be read so impermissibly broadly that the outer covering and inner core can be "slidably movable". This is an improper reading of the Applicants' claims. Claims are not be read in a vacuum but in view of

Applicants' specification. In view of Applicants' specification, it is plainly understood that the outer covering and inner core of independent Claims 1, 14 and 18 (and the remaining dependent claims) are immovable relative to each other. Such a reading is made necessary by the described purpose of the stylet in Applicants' specification.

There is no discussion or rationale in Applicants' specification that the inner core is movable from the outer covering once the stylet is assembled. While it is true that Applicants' specification mentions that the inner core may be inserted into the outer covering, this merely describes a process of manufacturing the stylet having an inner core and outer covering. It does not mean that the inner core is slidably movable relative to the outer covering. For this reason, Williams does not anticipate independent Claims 1, 14, and 18.

Claims 2 and 5-11 are dependent on Claim 1. Although there may be other reasons why Williams does not anticipate these dependent Claims 2 and 5-11, they are at least allowable because they depend on Claim 1, which is allowable.

Claim 17 is not anticipated, at least, although not necessarily only because of, its dependency on Claim 14.

Claim 13 rejected under 35 U.S.C. 102(b) or 103(a)

Claim 13 was rejected a second time under 35 U.S.C. 102(b) as anticipated by Williams or alternatively 103(a) as obvious over Williams. These rejections are respectively traversed.

Claim 13 is allowable by virtue of its dependence on Claim 1, which is in condition for allowance. In addition, Williams does not disclose that the core is pre-stressed. The Examiner states that "the core would inherently be required to be pre-stressed to achieve any sort of curvature during deployment." [Office Action, paragraph 16.] Absent any discussion in Williams to that effect, however, one must assume that the core is not pre-stressed. To the contrary, in order to have a core which is "pre-stressed", it must "operate on the compression side of the stress-strain curve." [Applicants' specification, paragraph 46, third sentence.] This element is missing in Williams, thereby precluding an anticipation rejection, and moreover, Applicants submit that making the inner core pre-stressed in a composite stylet is not an obvious modification, precluding an obviousness rejection.

Claim 3, 4, and 12 rejected under 35 U.S.C. 103(a)

Claims 3, 4, and 12 were rejected under 35 U.S.C. 103(a) as unpatentable over Williams. This rejection is respectfully traversed. Claims 3, 4 and 12 are all dependent on independent Claim 1, which is believed to be in condition for allowance. For that reason alone, although not necessarily the only reason, Claims 3, 4, and 12 are believed to be allowable.

Claim 15, 19, and 20 rejected under 35 U.S.C. 103(a)

Claims 15, 19 and 20 were rejected a second time under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Stoy et. al. (U.S. 5,217, 026, hereinafter referred to as "Stoy"). Applicants' Claim 15 depends from independent Claim 14, and Claims 19 and 20 depend from independent Claim 18. Williams does not make obvious independent Claims 14 and 18 because Williams teaches the use of a positioning device having multiple parts that are slidably movable relative to each other. Claims 14 and 18 describe, instead, a stylet that is a composite of an outer covering and inner core which are fixed relative to each other.

Stoy does not disclose a stylet having an outer covering that is metal. The outer covering is taught to be hydrogel. [See Stoy, abstract, and Claims 1-31.] As a preliminary matter, a prima facie case for combining Williams and Stoy requires some suggestion, motivation, rationale or advantage for combining the references. A prima facie case for combining the two references does not exist here. The purposes and functionality of each device described in Williams and Stoy are very different. Williams uses slidable moving elements that are not fixed relative to each other to provide a curved path through tissue. Stoy teaches a stylet with an outer covering of hydrogels to have a lubricious coating surface to avoid stylet or guidewire sticking. Separate movable elements are important in Williams. Apparently, there are no movable elements in Stoy and the outer covering is fixed or integral to the inner core [Stoy, column 4, line 5]. The two devices are conflicting in their function and their teaching. It

is not clear what motivation there is to substitute elements of Stoy with Williams or vice versa when the two devices provide teachings which are conflicting.

But even if combined, Stoy and Williams do not readily yield Claims 15, 19 or 20. Stoy suggests that the outer covering is not a metal but a hydrogel and the inner core material is a metal or sometimes a ceramic. Williams, suggests that the outer covering is a metal, but the inner core is also a metal. These references appear to contradict, not complement each other. There is no rationale given for mixing and matching elements, and essentially one must engage in cherry picking elements from Stoy and Williams to yield Applicants' claims. Neither Stoy and Williams, in themselves, suggests both an (1) an outer metal covering and (2) a non-metal inner core – which is Claim 15. In addition, the specific inner core material of “magnesia partially stabilized Zirconia, Yttria stabilized Zirconia, ceramic, epoxy and hard polyurethane, is not disclosed by Williams, although a ceramic inner core is disclosed by Stoy. Claim 15 also includes “the outer covering material is selected from the group consisting of cold drawn 304 stainless steel, 316 stainless steel, 316L stainless steel and nitinol (425 nickel-titanium)”. Such a specific combination of outer covering with inner core material cannot be arrived at except by engaging in impermissible hindsight reconstruction.

Hence, the (1) combination of Williams and Stoy does not meet a prima facie case of obviousness because of lack of motivation or suggestion in either to combine the two references. In addition, (2) to yield the correct combination of outer metal covering and non-metal inner core, one must cherry pick elements of Williams and Stoy to yield Claims 15, 19 and 20, and ignore the larger teachings of each reference, e.g.,

the use of hydrogel as an outer covering by Stoy, and the slidably movable pieces in Williams, which amounts to impermissible hindsight reconstruction.

For the reasons explained above, Williams and Stoy, in combination or by themselves, do not make obvious Applicants' Claims 15, 19 or 20, or for that matter, any of Applicants' claims. The §103(a) obviousness rejection to Claims 15, 19 and 20 is thus overcome.

By way of this Amendment B, in response to a §112 rejection, Claims 4 and 17 have been amended back to the form when this patent application was originally filed. All other rejections to Applicants' claims have been reiterated by the Examiner a second time. Applicants have traversed these rejections with new arguments. Because no other substantive amendments have been made to the claims, Applicants request entry of this Amendment B and reconsideration of the new arguments made herein.

As the total number of independent and dependent claims has not been changed with this Amendment B, no additional fees are believed due. Nonetheless, please charge any required fees or credit overpayment to **Deposit Account Number 50-0648.**

An early indication of allowability of pending Claims 1-20 is courteously requested. The Examiner is encouraged to telephone the undersigned to resolve any issues concerning this application.

Respectfully Submitted,

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Date

/PhilipHLee/
Philip H. Lee
Reg. No. 50,645
Attorney for Applicants

Please direct all written inquiries to:
Bryant R. Gold
Advanced Bionics Corporation
25129 Rye Canyon Road
Valencia, California 91355
Fax: (661) 362-1507

Please direct all telephone inquiries to:
Philip H. Lee
Telephone: (661) 362-1964